CJF-jlm-12/28/12

IN THE CIRCUIT COURT OF MARSHALL COUNTY WEST VIRGINIA

STATE OF WEST VIRGINIA, *ex rel.* DARRELL V. MCGRAW, JR., ATTORNEY GENERAL,

Plaintiff,

vs.

BRISTOL-MYERS SQUIBB COMPANY; SANOFI-AVENTIS U.S., LLC; SANOFI U.S. SERVICES, INC.; and SANOFI-SYNTHELABO, INC.,

Defendants.

Civil Action No. 12-C-266 H

COMPLAINT

COMES NOW, the Plaintiff, the State of West Virginia, by and through its Attorney General, acting in its sovereign capacity, and for its Complaint against Defendants Bristol-Myers Squibb Company; Sanofi-Aventis U.S., L.L.C.; Sanofi U.S. Services, Inc.; and Sanofi-Synthelabo, Inc., states and alleges as follows:

Introduction

1. This action arises out of Defendants' unfair and deceptive acts and practices and unfair methods of competition in wrongfully and illegally marketing, promoting, and selling their prescription blood thinner product Plavix® (clopidogrel bisulfate) (hereinafter referred to as "Plavix") in West Virginia. The Defendants have engaged in an illegal, deceptive marketing program throughout West Virginia to promote the use of Plavix by asserting without justification that Plavix was a superior drug to aspirin for certain indicated usages and charging the State approximately one hundred times more for Plavix than could be charged for aspirin despite Plavix having no better effect than aspirin for certain indicated usages. Defendants'

misrepresentations, omissions, and deceptive conduct have caused the State to spend significant amounts of State funds for the purchase and/or reimbursement of Plavix. As such, the State brings this action under the West Virginia Consumer Credit and Protection Act ("WVCCPA"), under State law governing the Public Employees Insurance Agency, in common law, and at equity, seeking equitable relief to restrain Defendants from continuing to engage in their deceptive marketing program, and disgorgement of all monies received by Defendants as a result of the conduct complained of herein, restitution, civil penalties, attorneys' fees, costs, and all other relief to which it may be justly entitled.

2. The claims sought herein seek relief which inure to the State of West Virginia alone and no claim asserted herein is brought for any individual person who has been damaged by reason of Defendants' conduct. The claims asserted herein are brought solely by the State of West Virginia and are wholly independent of any claims that individual users of Plavix may have against Defendants.

Parties

3. The State is a body politic created by the Constitution and laws of the State of West Virginia and, as such, it is not a citizen of any state. Darrell V. McGraw, Jr. is the State's duly-elected and present Attorney General and brings this action on the State's behalf pursuant to the authority granted to him, *inter alia*, by W.Va. Code §§ 46A-7-108 and 46A-7-111(2).

4. Defendant Bristol-Myers Squibb Company ("BMS") is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters in New York, New York. BMS is authorized to conduct business in West Virginia and its registered agent for service of process is CT Corporation System, 5400 D Big Tyler Road, Charleston, West Virginia 25313.

5. Defendant BMS includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, its predecessors, successors, and assigns and its present officers, directors, employees, agents, representatives, and any other persons acting on its behalf.

6. At all times material herein, Defendant BMS transacted business within the State of West Virginia by promoting, marketing, distributing and/or selling Plavix to the State of West Virginia, its departments, agencies, instrumentalities, and/or contractors.

7. Defendant Sanofi-Aventis U.S., L.L.C. is a limited liability company organized and existing under the laws of the State of Delaware with its corporate headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S., L.L.C. is authorized to conduct business in West Virginia and its registered agent for service of process is Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302.

8. Defendant Sanofi U.S. Services, Inc. is a corporation organized and existing under the laws of Delaware with corporate offices located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi U.S. Services, Inc. is authorized to conduct business in West Virginia and its registered agent for service of process is Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302.

9. Defendant Sanofi-Synthelabo, Inc. is a corporation organized and existing under the laws of the State of Delaware with corporate offices in Bridgewater, New Jersey.

10. Defendants Sanofi-Aventis U.S., L.L.C.; Sanofi U.S. Services, Inc.; and Defendant Sanofi-Synthelabo, Inc. are hereinafter referred to collectively as "Sanofi."

11. At all times material herein, Defendant Sanofi transacted business within the State of West Virginia by promoting, marketing, distributing and/or selling Plavix to the State of West Virginia, its departments, agencies, instrumentalities, and/or contractors.

12. Defendant Sanofi includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, its predecessors, successors, and assigns and its present officers, directors, employees, agents, representatives, and any other persons acting on its behalf.

13. Upon information and belief, in committing the acts alleged herein, each and every managing agent, agent, representative, and/or employee of the Defendants was working within the course and scope of said agency, representation and/or employment, and said acts were authorized, ordered, done and/or ratified by Defendants' directors, officers, agents, employees, or representatives while engaged in the management, direction, control or transaction of Defendants' business affairs.

Jurisdiction and Venue

14. This Court has subject matter jurisdiction over the claims asserted herein pursuant to Article VIII, Section 6 of the West Virginia Constitution and W.Va. Code § 51-2-2. The Attorney General has the power to bring these claims on behalf of the State under the provisions of W.Va. Code §§ 46A-7-101, *et seq.*

15. This Court has personal jurisdiction over the Defendants because they conduct business in West Virginia and have committed acts in West Virginia causing tortious injury.

16. Venue and personal jurisdiction is proper in Marshall County, West Virginia, because Defendants conducted business in Marshall County, individually or in conjunction with others, by supplying, marketing, selling, promoting, advertising, and otherwise

distributing Plavix in Marshall County. Accordingly, the cause of action arose, in part, in Marshall County, West Virginia.

17. Venue is also proper in this County pursuant to W.Va. Code §§ 46A-7-114 and 56-1-1(a) in that the violations of law alleged in this Complaint occurred throughout the State of West Virginia, including within Marshall County.

Factual Allegations

18. Plavix® (clopidogrel bisulfate) ("Plavix") is a prescription blood thinner manufactured by BMS and co-marketed in the United States and in West Virginia by Sanofi (hereinafter referred to collectively as "BMS/Sanofi"). Plavix was first approved by the FDA on November 17, 1997 for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease ("PAD"). Several years later, on February 27, 2002, the FDA approved Plavix for the treatment of patients with Acute Coronary Syndrome (unstable angina/non-ST elevation myocardial infarction), also known as "NSTEMI." On August 17, 2006, the FDA approved Plavix for the treatment of patients with Acute Coronary Syndrome (ST-elevation myocardial infarction), also known as "STEMI."

19. Plavix is BMS's number one selling product and has been the second highest grossing prescription medicine in the world for the past several years. The reported worldwide revenue for Plavix in 2011 was $9.5 Billion with sales in the United States accounting for $7 Billion. Plavix lost patent protection on November 17, 2011.

20. Defendants Sanofi/BMS have a marketing partnership under which they jointly market Plavix throughout the United States including West Virginia. Since March of 1998, Plavix has been marketed exclusively in the United States and West Virginia by BMS/Sanofi through the marketing partnership agreement. All efforts to promote Plavix are jointly

administered by BMS/Sanofi. All advertisements, brochures, and promotional materials for Plavix feature both the BMS and Sanofi names.

21. At all times material herein, BMS/Sanofi engaged in an illegal marketing program in West Virginia to promote the use of Plavix by affirmatively representing that Plavix was a superior drug to aspirin for certain indicated usages when in fact Plavix was no more effective than aspirin for certain indicated usages.

22. Upon information and belief, BMS/Sanofi misrepresented the efficacy of Plavix as justification to charge a higher price, thereby increasing company profits. BMS/Sanofi charged approximately one hundred times more for Plavix than the cost of aspirin. Plavix costs approximately $4.00 per pill whereas aspirin costs approximately $0.04 per pill.

23. Upon information and belief, BMS/Sanofi targeted their false and deceptive marketing efforts at the State and beneficiaries of the Public Employees Insurance Agency (hereinafter "PEIA"). As a result of BMS/Sanofi's efforts and exploitation, the State has spent significant amounts of State funds in purchasing Plavix with no additional benefit to the covered patient/beneficiary, when compared to aspirin.

24. By making fraudulent claims regarding Plavix's efficacy compared to aspirin, BMS/Sanofi convinced many physicians of Plavix's false superiority to aspirin and its unique qualities. This scheme left many physicians with the false impression that Plavix was essentially the only option for effective patient care in a host of contexts.

25. At all times material herein, BMS/Sanofi knew or should have known that Plavix was no better for certain indicated usages than aspirin but, nonetheless, used its substantial sales, marketing, and public relations machines to create a false and misleading impression of Plavix's efficacy among the State and beneficiaries of the PEIA.

26. Since 2007, BMS/Sanofi has spent millions of dollars on Direct to Consumer ("DTC") print and television advertising and other means, aimed at convincing beneficiaries of the PEIA to request Plavix from their doctors. BMS/Sanofi's marketing campaign also targeted prescribers as well as the individuals, groups, and entities responsible for selecting the drugs covered by coverage plans and/or included on pharmacy formularies. BMS/Sanofi sought to influence these targets through, among other tactics, print, television, and radio media; press releases; sales calls and presentations; and misleading promotional materials.

27. Upon information and belief, BMS/Sanofi has at all relevant times herein known that it lacked the scientific data to support their efficacy claims about Plavix. BMS/Sanofi manipulated clinical trial data to support fraudulent claims regarding Plavix's efficacy relative to cheaper alternatives, such as aspirin. BMS/Sanofi mischaracterized clinical studies which contradicted the sales campaign because they needed justification for the steep price difference between Plavix and aspirin. BMS/Sanofi then promoted this false narrative regarding Plavix's efficacy compared to cheaper alternatives like aspirin to physicians and health-care providers.

28. By at least 2006, BMS/Sanofi knew that its efficacy claims concerning Plavix were false, deceptive, and misleading.

29. From the beginning, BMS/Sanofi knew or should have known that a significant percentage of patients were genetically predisposed to have substantially diminished or no responsiveness to Plavix. BMS/Sanofi was required by law to disclose this information but failed to do so because such information would lead to a reduction in the number of prescriptions being written for Plavix, thereby resulting in a decline in sales and revenue.

30. By the end of 2006, it was clear to the scientific community that (i) Plavix must be transformed into an active metabolite by CYP enzymes in order for it to have the desired

anti-platelet effect; (ii) the CYP2C19 enzyme plays an important role in metabolizing Plavix, (iii) the genes encoding the CYP enzymes are polymorphic, meaning that they contain multiple alleles; and (iv) common alleles of that CYP enzyme genes lead to reduced functionality, and thus diminished or no responsiveness to Plavix.

31. Upon information and belief, BMS/Sanofi failed to bring this to the attention of any regulatory body or physicians to whom they were promoting the drug.

32. Moreover, BMS/Sanofi responded to the adverse efficacy data by proactively encouraging physicians to prescribe higher doses of Plavix to affected patients, representing that the higher doses would counteract the diminished functionality of the patient's CYP system enzymes. BMS/Sanofi knew that if the medical community was fully informed that as much as 30% of the patient population was genetically predisposed to have diminished or no response to Plavix, then physicians would treat those patients using alternate therapies instead of Plavix.

33. Additionally, at all times material herein, BMS/Sanofi manipulated clinical trial data to support its fraudulent claims regarding Plavix's efficacy compared to cheaper alternatives such as aspirin.

34. Specifically, BMS/Sanofi improperly lumped together different patient trial groups to support its false and misleading claim of superiority over aspirin. BMS/Sanofi further falsely promoted the results of the *Clopidogrel vs. Aspirin in Patients at Risk for Ischemic Events* ("CAPRIE") study and failed to represent the results of the CAPRIE study in a fair and balanced manner.

35. Plavix is indicated for treatment of patients who have recently suffered from a stroke. This indication was initially obtained based on the CAPRIE clinical trial conducted on

or about November 16, 1996. The CAPRIE trial enrolled 19,185 patients with approximately 6,300 patients in each of three different subgroups. Those three subgroups included (i) patients who experienced a recent stroke, (ii) patients who experienced a recent myocardial infarction (MI), and (iii) patients who experienced recent peripheral arterial disease (PAD). In each subgroup, half of the patients were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix daily.

36. The primary efficacy endpoint for the CAPRIE trial was the combination of ischemic stroke, MI, or vascular death. Put another way, in each of these three subgroups, the trial compared the combined rates of ischemic stroke, myocardial infarction, and vascular death between patients receiving Plavix against those receiving aspirin to determine whether Plavix was more or less effective in preventing those events, i.e., ischemic stroke, MI, and vascular death. In the CAPRIE trial, Plavix demonstrated a marginally significant 8.7% relative risk reduction of the primary endpoint point compared to aspirin. The absolute risk reduction was 0.5%, meaning that for every 1,000 patients treated with Plavix, only five patients benefited from Plavix as compared to aspirin treatment.

37. The CAPRIE composite data was driven primarily by the peripheral arterial disease (PAD) subgroup which showed a relative risk reduction of 23.8% in the primary endpoint. However, in the recent stroke and recent myocardial infarction subgroups, CAPRIE demonstrated that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin. In the case of aspirin, even though no statistically significant reduction existed favoring aspirin over Plavix for recent myocardial infarctions, the study concluded the trend favored aspirin over Plavix.

38. This subgroup information was included in the CAPRIE Road Map which was used for sales training. The CAPRIE Road Map was intended to be used for internal sales training and was not to be used in sales presentations to doctors or other prescribers. On pamphlets provided to physicians summarizing the CAPRIE study, however, the subgroup analysis was not provided. Only the overall 8.7% reduction in the primary endpoint was provided. Had the subgroup analysis been included, it would have demonstrated that in two of the three subgroups (recent stroke and recent myocardial infarction patients), Plavix failed to reduce the instances of ischemic stroke, MI, or vascular death any more than simple treatment with aspirin.

39. Despite the non-significant efficacy data in the CAPRIE trial for stroke patients, company sales pamphlets (citing CAPRIE) claimed that there was "proven efficacy" of Plavix over aspirin in ischemic stroke patients.

40. Further tests regarding Plavix yielded similar results as the CAPRIE trial. On April 20, 2006, the results of the CHARISMA trial concluded as follows: "Overall, clopidogrel [Plavix] plus aspirin was not significantly more effective than aspirin alone in reducing the rate of myocardial infarction, stroke, or death from cardiovascular causes."

41. Additionally, when Plavix was initially approved by the BMS Advisory Board Committee on October 24, 1997, the report included the following disclaimer:

> "I think that given our concern about the selection of endpoints, some concerns about the follow-up and certain concerns about the marginality of the *p* value, we are very reluctant to conclude that clopidogrel is superior to aspirin. I think you can wordsmith this any way you feel comfortable doing."

42. Defendants have further falsely and deceptively promoted Plavix as superior to Aggrenox. Aggrenox (aspirin + dipyridamole) is recommended over Plavix for stroke patients

in the 2010 ASA Guidelines. The efficacy and safety of Aggrenox versus aspirin is supported by three large clinical trials, whereas only one clinical trial (CAPRIE) compares Plavix with aspirin. The *Prevention Regimen for Effectively Avoiding Second Strokes* ("PRoFESS") trial compared Aggrenox with Plavix in the prevention of secondary stroke in patients who have experienced a recent stroke.

43. According to the ASA, the PRoFESS trial "showed no difference in stroke recurrence among patients assigned to [Plavix] compared with patients assigned to [Aggrenox]." There was also no statistically significant difference between the two drugs in causing major hemorrhagic events. However, BMS/Sanofi presented the PRoFESS data in a manner designed to confuse physicians and influence an unsupported belief that Aggrenox was inferior to Plavix.

44. Rather than state that PRoFESS showed no difference between the two drugs, BMS/Sanofi trained and instructed its sales force to emphasize that "Aggrenox failed to meet the primary end point of noninferiority for recurrent stroke relative to Plavix." BMS/Sanofi further trained its sales representatives to claim that it "should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients." Despite the inconclusiveness of the PRoFESS data, the ASA still recommends Aggrenox over Plavix due to substantially more clinical data favoring its use in stroke patients.

45. As a result of BMS/Sanofi's systematic and deliberate promotion of Plavix through false and misleading advertising which overstated its efficacy and advanced unsubstantiated superiority claims, the FDA issued multiple Warning Letters to BMS/Sanofi relating to its promotion of Plavix.

46. On December 19, 1998, BMS/Sanofi received a warning letter from AdCom-DDMAC, stating as follows: "Therefore, claims that suggest that Plavix has been 'proven' to be more effective than aspirin are **misleading** because they are not based on substantial evidence" (emphasis added). The letter concluded as follows: "**Sanofi should immediately cease distribution of these promotional materials, and all other promotional materials for Plavix that contain the same or similar claims or presentations**" (emphasis added).

47. On May 5, 2001, BMS/Sanofi received yet another warning letter from DDMAC, stating as follows:

> "On page 4 of the visual aid you present the claim, 'Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients.' This claim is **misleading** because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. As previously stated in our December 18, 1998, untitled letter, the **CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superior efficacy over aspirin**. Therefore, claims suggesting that Plavix is significantly better than aspirin are **misleading because they are not based on substantial evidence**" (emphasis added).

48. Nonetheless, BMS/Sanofi blatantly ignored these warnings and continued to illegally and deceptively market, promote, and sell Plavix throughout the country and in West Virginia at all times material herein. Moreover, upon information and belief, BMS/Sanofi trained its sales representatives to misrepresent the data and studies and told its sale representatives to assert that the efficacy was "proven" when compared to aspirin.

49. BMS/Sanofi's claim of "proven efficacy" of Plavix over aspirin in ischemic stroke patients was rebutted in 2010 when the ASA's *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* were amended to state, "No studies have compared clopidogrel with placebo, and studies comparing it with other antiplatelet agents have not clearly established that it is superior or even equivalent to any of them."

50. The 2010 ASA guidelines recommend the use of Plavix for the treatment of stroke patients only if the patient is allergic to aspirin. The 2010 ASA guidelines provide a Class I; Level of Evidence A recommendation for the use of aspirin in the secondary prevention of stroke. The guidelines only provide a Class IIA, Level of Evidence B recommendation for the use of Plavix in the secondary prevention of stroke. Class I means that a treatment should be administered. Class IIA means that additional studies with focused objectives are needed, but that it is reasonable to administer treatment. Nonetheless, BMS/Sanofi ordered its personnel to promote Plavix as being superior to aspirin in stroke patients. As a result, Plavix was regularly and systematically presented to physicians as superior to aspirin for treatment of stroke patients.

51. BMS/Sanofi also encouraged physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin. According to the ASA, however, "there have been no clinical trials to indicate that switching anti-platelet agents reduces the risk for subsequent events."

52. By falsely and deceptively marketing Plavix in West Virginia, BMS/Sanofi engaged in unfair methods of competition and unfair or deceptive acts and practices in or affecting commerce in the State of West Virginia.

53. BMS/Sanofi engaged in unfair, deceptive, and misleading practices in an attempt to influence prescribers, the State and beneficiaries of the PEIA to believe that Plavix was a superior drug compared to cheaper alternates such as aspirin when it was not.

54. BMS/Sanofi willfully made false statements and concealed material facts regarding the efficacy of Plavix in order to influence the State to pay for Plavix.

55. BMS/Sanofi's false and deceptive marketing has caused the State of West Virginia to pay a hefty premium by overpaying for a drug that was no more efficacious than far cheaper alternatives.

56. The State of West Virginia seeks the most effective treatment for its residents and relies on pharmaceutical companies to fairly and accurately represent the efficacy of their products. BMS/Sanofi has wholly violated that trust and, instead, engaged in unfair methods of competition and unfair and deceptive acts and practices by making false representations that Plavix was better for certain indicated usages than far cheaper alternatives such as aspirin. This has caused the State of West Virginia to needlessly spend significant sums of State funds. As between the State of West Virginia and BMS/Sanofi, all increased costs caused by BMS/Sanofi's conduct should be borne by BMS/Sanofi and not the State of West Virginia.

57. The averments set forth in Paragraphs 1 through 56 of this Complaint are hereby incorporated by reference in each Count of this Complaint as if set forth in their entirety.

COUNT I

Violation of the West Virginia Consumer Credit and Protection Act

58. Article 6 of the West Virginia Consumer Credit and Protection Act, entitled "General Consumer Protection," is designed to protect the public from unfair, deceptive and fraudulent acts and practices. W.Va. Code §§ 46A-6-101 to -110, 46A-7-101, *et seq.* "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are [] declared unlawful" in the State of West Virginia. *Id.* at 46A-6-104.

59. The Attorney General of the State of West Virginia is specifically charged with administration of West Virginia Code §§ 46A-7-102 *et seq.*, and may act *sua sponte* as the

agent and legal representative of the State in civil proceedings to enforce the statute. W.Va. Code §46A-6-103, §§ 46A-7-102, -108, -109, -110, -111.

60. Violations of statutes enacted to protect the consuming public or in the exercise of the State's police power constitute unfair or deceptive acts or practices.

61. Among other things, W.Va. Code § 46A-6-102 defines "unfair methods of competition and unfair or deceptive acts or practices" as, but not limited to, the following:

> (B) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;
>
> (C) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with or certification by another;
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> * * * *
>
> (E) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;
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> * * * *
>
> (G) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model if they are of another;
>
> (H) Disparaging the goods, services or business of another by false or misleading representation of fact;
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> * * * *
>
> (L) Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;
>
> (M) The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby; [and]
>
> (N) Advertising, printing, displaying, publishing, distributing or broadcasting, or causing to be advertised, printed, displayed, published, distributed or

> broadcast in any manner, any statement or representation with regard to the sale of goods or the extension of consumer credit including the rates, terms or conditions for the sale of goods or the extension of consumer credit including the rates, terms or conditions for the sale of such goods or the extension of such credit, which is false, misleading or deceptive or which omits to state material information which is necessary to make the statements therein not false, misleading or deceptive[.]

Id. at §46A-6-102.

62. By labeling, distributing, marketing, promoting, advertising and selling Plavix BMS/Sanofi has engaged in unfair methods of competition and unfair and deceptive acts and practices in the conduct of trade and commerce within the State, and specifically in Marshall County, West Virginia as prohibited by W.Va. Code § 46A-6-104.

63. BMS/Sanofi has repeatedly, knowingly, and willfully engaged in the following conduct described herein which constitutes an unfair method of competition and/or an unfair or deceptive act or practice and a violation of the West Virginia Consumer Credit and Protection Act.

64. BMS/Sanofi's misrepresentations in violation of the West Virginia Consumer Credit and Protection Act include, but are not limited to, the following: BMS/Sanofi represented that Plavix was an effective drug when it knew or should have known that such representations were untrue, false, or misleading; it represented that Plavix was a more effective drug than its competitors when it knew or should have known that such representations were untrue, false, or misleading; and it represented that Plavix was "proven" to be more effective than aspirin in the treatment of certain indicated usages when it knew or should have known that such representation was untrue, false, or misleading. By failing to disclose and omitting material facts, BMS/Sanofi further engaged in deceptive and fraudulent practices in violation of the Act.

65. BMS/Sanofi made, orally and in writing, false, misleading, or deceptive representations in advertisements, promotions, marketing materials, statements, and product labeling for Plavix to prescribers, the State and beneficiaries of the PEIA regarding the efficacy associated with using Plavix. BMS/Sanofi continues to make, orally and in writing, such false, misleading, or deceptive representations in statements regarding Plavix.

66. BMS/Sanofi acted knowingly and willfully in committing the violations of the West Virginia Consumer Credit and Protection Act described herein. Each violation of the statute by BMS/Sanofi is an unfair and deceptive act or practice in the conduct of trade or commerce in violation of West Virginia Code § 46A-6-104 and constitutes a separate, distinct, knowing and willful violation of the West Virginia Consumer Credit and Protection Act. BMS/Sanofi's willful violations justify assessing civil penalties of up to $5,000 for each violation of the Act as authorized under W.Va. Code § 46A-7-111(2).

67. The Attorney General has determined that BMS/Sanofi is using and has used methods, acts and practices prohibited by the West Virginia Consumer Credit and Protection Act and that equitable relief in the form of the imposition of an injunction against BMS/Sanofi prohibiting the conduct set forth herein and disgorgement of all monies received by BMS/Sanofi as a result of the conduct complained of herein is in the public interest. The State is seeking both disgorgement and the entry of a permanent injunction prohibiting BMS/Sanofi's conduct in violation of the West Virginia Consumer Credit and Protection Act.

COUNT II

Misrepresentations to the Public Employees Insurance Agency

68. Subsection (a) of W.Va. Code § 5-16-12 states:

> "Any person who knowingly secures or attempts to secure benefits payable under this article or anything of value to which

> the person is not entitled, or who knowingly secures or attempts to secure greater benefits than those to which the person is entitled, by willfully misrepresenting the presence or extent of benefits to which the person is entitled under a collateral insurance source, or by willfully misrepresenting any material fact relating to any other information requested by the director or by willfully overcharging for services provided, or by willfully misrepresenting the diagnosis or nature of the service provided, may be found to be overpaid and shall be civilly liable for any overpayment. In addition to the civil remedy provided herein, the director shall withhold payment of any benefits or other payment due to that person until any overpayment has been recovered or may directly set off, after holding internal administrative proceedings to assure due process, any such overcharges or improperly derived payment against benefits or other payment due such person hereunder. Nothing in this section shall be construed to limit any other remedy or civil or criminal penalty provided by law."

69. In representing that Plavix had superior efficacy than other established and cheaper drugs, BMS/Sanofi committed violations of W.Va. Code § 5-16-12 in connection with benefits offered by the PEIA. On information and belief, BMS/Sanofi's clinical research and publication strategies were directed and influenced largely by marketing concerns, BMS/Sanofi improperly and deceptively influenced the medical and scientific literature and the perception of Plavix within the medical community; it formed deceptive and misleading promotional relationships with prescribers and physicians for the purpose of promoting the product; it engaged in misleading sales training, sales tactics, and marketing to prescribers, beneficiaries of the PEIA and the State of West Virginia that misrepresented the efficacy of Plavix; and it engaged in other deceptive and misleading marketing, lobbying, public relations and sales practices as described herein.

70. In addition, BMS/Sanofi, through its control and manipulation of studies and research publications, and its false and deceptive marketing conducted by BMS/Sanofi sales representatives, caused false and misleading information regarding the efficacy of Plavix to be

reasonably relied upon by prescribers within West Virginia, the State, the PEIA and beneficiaries of the PEIA.

71. BMS/Sanofi caused the PEIA to pay for the use of Plavix by willfully misrepresenting the nature of Plavix – namely the efficacy of the drug. Because of BMS/Sanofi's illegal conduct, the PEIA has paid significant amounts of money for the use of Plavix.

72. Accordingly, under W.Va. Code § 5-16-12, the Attorney General, on behalf of the PEIA, is entitled to recover the amount of money the PEIA spent on Plavix.

COUNT III

Violation of the Insurance Fraud Prevention Act

73. "Any person who knowingly and willfully and with intent to defraud submits a materially false statement in support of a claim for insurance benefits or payment pursuant to a policy of insurance or who conspires to do so is..." in violation of the Insurance Fraud Prevention Act. W.Va. Code § 33-41-11.

74. In representing that Plavix had superior efficacy than other established drugs, and in failing to disclose the true facts regarding the efficacy of Plavix, BMS/Sanofi committed violations of W.Va. Code § 33-41-11 in connection with benefits offered and payments made by the PEIA. On information and belief, BMS/Sanofi's clinical research and publication strategies were directed and influenced largely by marketing concerns. BMS/Sanofi improperly and deceptively influenced the medical and scientific literature and the perception of Plavix within the medical community; it formed deceptive and misleading promotional relationships with prescribers and physicians for the purpose of promoting the product; it engaged in misleading sales training; sales tactics, and marketing to prescribers, beneficiaries

of the PEIA, and the State of West Virginia that misrepresented the efficacy of Plavix; and it engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described within.

75. In addition, BMS/Sanofi, through its control and manipulation of studies and research publications, and its false and deceptive marketing conducted by BMS/Sanofi sales representatives, caused false and misleading information regarding the efficacy of Plavix to be reasonably relied upon by the State and the PEIA.

76. BMS/Sanofi is subject to a civil penalty of up to ten thousand dollars per violation of the Insurance Fraud Prevention Act. W.Va. Code § 33-41-12(1). The civil penalty is mandatory and not subject to suspension. *Id.* at § 33-41-12(2). Accordingly, the Attorney General is entitled to recover a penalty of up to $10,000.00 for each of BMS/Sanofi's violations of the Insurance Fraud Prevention Act.

COUNT IV

Unjust Enrichment

77. BMS/Sanofi knowingly, willfully, and intentionally marketed and promoted Plavix in a false and deceptive manner.

78. BMS/Sanofi knowingly, willfully and intentionally withheld information from the State and beneficiaries of the PEIA regarding the efficacy of Plavix.

79. The State paid, reimbursed or otherwise conferred a benefit upon BMS/Sanofi that directly resulted from BMS/Sanofi's fraudulent marketing practices.

80. BMS/Sanofi knowingly accepted such benefit, to which it is not entitled. BMS/Sanofi has been unjustly enriched as a result of its fraudulent marketing practices.

81. BMS/Sanofi's acceptance and retention of such benefit under these circumstances is unjust and inequitable.

82. As a matter of equity and West Virginia common law, the State should be made whole by application of the doctrine of unjust enrichment. The State is entitled to restitution to the extent of the increased revenue received by BMS/Sanofi from Plavix prescriptions that were reimbursed by the State via the PEIA which resulted from BMS/Sanofi's deceptive and illegal marketing program.

COUNT V

Fraud and Negligent Misrepresentation

83. BMS/Sanofi's representations of the efficacy of Plavix contained false representations and/or failed to accurately represent the material facts of the efficacy of the drug.

84. BMS/Sanofi's Plavix-related claims and assertions to the State and beneficiaries of the PEIA contained false representations as to the efficacy of Plavix.

85. BMS/Sanofi was negligent and/or reckless in not making accurate representations regarding the efficacy of Plavix.

86. BMS/Sanofi knew or reasonably should have known that the claims made to the State and beneficiaries of the PEIA with regard to the efficacy of Plavix were false or incomplete, and misrepresented the facts about Plavix.

87. The State, through the PEIA program, expended significant amounts of state funds for Plavix prescriptions which were directly caused by the fraudulent and misleading statements of the Defendants.

88. Defendants willfully, knowingly and deceptively withheld material facts regarding the efficacy of Plavix from the State and beneficiaries of the PEIA.

89. Defendants intentionally withheld information regarding the efficacy of Plavix with the intent to induce the State and beneficiaries of the PEIA.

90. The State of West Virginia, prescribers, and PEIA participants and/or beneficiaries were justified in their reliance on Defendants to educate them as to the efficacy of Plavix use.

91. BMS/Sanofi's far-reaching, massive and widespread promotional campaign to drive Plavix sales was specifically directed at and did influence the State. BMS/Sanofi sales representatives directly communicated with the State, and in connection therewith, presented false and misleading information regarding the efficacy of Plavix which was reasonably relied upon by the State of West Virginia.

92. In addition, BMS/Sanofi through its control and manipulation of studies and its false and deceptive marketing conducted by BMS/Sanofi sales representatives caused false and misleading information regarding the efficacy of Plavix to be reasonably relied upon by the State of West Virginia.

93. BMS/Sanofi's aggressive, illegal promotions have induced a misallocation of PEIA funds through a pattern of fraudulent conduct which caused false claims to be submitted to the PEIA. Defendants executed and conspired to execute a plan to defraud the State and the PEIA in connection with the delivery of or payment for Plavix. Defendants' plan included the implementation of intentionally deceptive marketing schemes. Defendants intended that their fraudulent promotion result in the reimbursement of prescriptions by the State through the PEIA.

94. Each of the Defendants' misleading and deceptive statements, representations and advertisements related to Plavix were material to the State's reimbursement of Plavix.

95. As a proximate and legal result of BMS/Sanofi's fraudulent misrepresentations, the State of West Virginia has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

Punitive Damages

96. The acts, omissions, and conduct of BMS/Sanofi as described herein were willful, wanton, and malicious and/or reckless and/or done with criminal indifference to the civil rights of others and warrant the assessment of punitive damages.

97. Punitive damages are justified to punish BMS/Sanofi for their willful, wanton, malicious, and reckless behavior and will serve to deter these Defendants, as well as other reckless pharmaceutical companies, from conducting business in West Virginia in this manner and profiting from such reprehensible conduct.

WHEREFORE, the State of West Virginia, by and through its Attorney General, respectfully prays that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against BMS/Sanofi;

2. Enjoining BMS/Sanofi and its employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in unfair or deceptive acts or practices in violation of West Virginia law and ordering temporary, preliminary or permanent injunction;

3. Awarding judgment against BMS/Sanofi for restitution and disgorgement of monies under the general equitable powers of this Court, the doctrine of unjust enrichment, pursuant to the West Virginia Consumer Credit and Protection Act and any other authority;

4. Awarding the State all damages sustained by it in connection with the PEIA;

5. Declaring that each act of BMS/Sanofi described in this Complaint constitutes a separate violation of West Virginia law;

6. Imposing civil penalties of up to $5,000.00 for each repeated and willful violation of Chapter 46A under West Virginia Code § 46A-7-111(2);

7. Ordering BMS/Sanofi to pay the State the amount of the benefits paid by the PEIA as a result of BMS/Sanofi's wrongful conduct, as allowed under W.Va. Code § 5-16-12(a);

8. Imposing civil penalties of up to $10,000.00 per violation of the Insurance Fraud Prevention Act. W.Va. Code § 33-41-12(1);

9. Awarding equitable relief, including, but not limited to restitution and disgorgement of monies obtained as a result of BMS/Sanofi's unfair or deceptive acts and practices and misrepresentations and omissions;

10. Awarding the State an amount of punitive damages determined by a jury according to the laws of the State of West Virginia; and

11. Granting the State:

    a. The cost and attorney fees expended in the prosecution of this matter;

    b. Pre-judgment and post-judgment interest as provided under the law;

    c. Any and all further relief as a court and/or jury deem just and proper.

The minimum jurisdictional amount established for filing this action is satisfied.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Respectfully submitted,

STATE OF WEST VIRGINIA, *ex rel.*
DARRELL V. MCGRAW, JR.,
ATTORNEY GENERAL,

By: _____

Frances A. Hughes (WV Bar ID # 1816)
Chief Deputy Attorney General
Office of the Attorney General
Building 1, Room 26-E
Capitol Complex
Charleston, WV 25305
Telephone: (304) 558-2021
Fax: (304) 558-0140

Robert P. Fitzsimmons (WV Bar # 1212)
Clayton J. Fitzsimmons (WV Bar # 10823)
FITZSIMMONS LAW FIRM PLLC
1609 Warwood Avenue
Wheeling, WV 26003
Telephone: (304) 277-1700
Fax: (304) 277-1705
bob@fitzsimmonsfirm.com
clayton@fitzsimmonsfirm.com

Carl N. Frankovitch (WV Bar #4746)
Mark A. Colantonio (WV Bar # 4238)
FRANKOVITCH, ANETAKIS
COLANTONIO & SIMON
337 Penco Road
Weirton, WV 26062
Telephone: (304) 723-4400
Fax: (304) 723-5892
carl@facslaw.com
mark@facslaw.com

Robert L. Salim (#11663) (Motion for Admission *Pro Hac Vice* to be filed)
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457
Telephone: (318) 352-5999
Fax: (318) 354-1227

Teresa C. Toriseva (WV Bar ID # 6947)
TORISEVA LAW
1446 National Road
Wheeling, WV 26003
Telephone: (304) 238-0066
Facsimile: (304) 238-0149
tct@torisevalaw.com